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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,947	12/22/2005	Harumi Minekawa	Q91103	7981

23373 7590 06/18/2007

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EXAMINER	
BABIC, CHRISTOPHER M	
ART UNIT	**PAPER NUMBER**
1637	

MAIL DATE	DELIVERY MODE
06/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,947	MINEKAWA ET AL.	
	Examiner	Art Unit	
	Christopher M. Babic	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7 and 11-20* is/are pending in the application.

4a) Of the above claim(s) *1-4,8-10,13,15,18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,11,12,14,16,17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/22/05 ; 4/5/2007
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Applicant's election without traverse of group II, claim(s) 5-7 and 11-20 in the reply filed on March 19, 2007 is acknowledged.

Applicant's election with traverse of primer set B, SEQ ID NOs: 17, 18, 10, 19, 22, and 23 is acknowledged. The traversal is on the ground(s) that there is not an undue burden on the Examiner. This is not found persuasive because the **claimed** invention does not require the presence of four primer sequences recited in four SEQ ID NOs, i.e. the **claimed** invention does not require the presence of a collection of SEQ ID NOs. In fact, claim 6 is the only claimed embodiment that actually requires four primers, i.e. the claim requires amplification through the LAMP method, and only one of those primers is required to meet the limitations of claim 1. Each SEQ ID NO recited within the **claimed** invention represents an independent and distinct sequence, and each SEQ ID NO must be evaluated, i.e. search and examined, on its own merit. Any unnecessary searching places an undue burden on not only the Examiner, but also the resources of the Office. Combination and subcombinations material to patentability will be searched as recited in MPEP 803.04, however, the current invention does not require the combination of primer sets A or B. If the combination of the specific primer sequences within primer sets A or B become material to patentability due to any amendment made throughout the prosecution of the claimed method, the Examiner will consider examination of both primer sets. Thus, the requirement is still deemed proper and is therefore made FINAL.

In an interview with Applicant on February 16, 200, the Examiner did agree to an election of multiple SEQ ID NOs, however, only SEQ ID NO:10 (readable on claim 2) is applicable to the current examination. Claim(s) 1-4, 8-10, 13, 15, 18, and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Interpretation

It is noted that, as understood by the Examiner, Applicant intends to design primers complementary to a sequence found within nucleotides 41 to 256 of SEQ ID NO: 1, however, the phrase, ----**designed based on any nucleotide sequence** selected from 41 to 256 of the nucleotide sequence of an RNA polymerase of the SARS virus as shown in SEQ ID NO: 1--, as recited within claim 1, can be interpreted to encompass a variety of different oligonucleotide primer sequences having as little as a one base "relationship" to the sequence of SEQ ID NO: 1. First, the phrase ---designed based on-- does not necessarily mean "in common" or "complementary." Second, the phrase --any nucleotide sequence-- encompasses as little as **one** nucleotide base. Thus, a primer having **one** base in common or complementary to **one** base of nucleotides 41 to 256 of SEQ ID NO: 1 is encompassed by the claim language of claim 1.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 5-7, 11, 12, 14, 16, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim(s) 5-7, 11, 12, 14, 16, 17, and 19 are indefinite because it is unclear whether the phrase --a nucleotide sequence complementary thereto--, as recited in claim 1, is referencing nucleotides 41-256 of SEQ ID NO: 1, **or**, the full-length of SEQ ID NO: 1.

(b) Claim(s) 11 and 16 are indefinite because it is unclear whether the phrase --a nucleotide sequence complementary thereto--, as recited in claim 2, is referencing 15 contiguous nucleotides from SEQ ID NO: 10 (elected sequence), **or**, the full-length of SEQ ID NO: 1.

(c) Claim(s) 12, 14, 17, and 19 refer to sequence regions F3c, F2c, F1c, R3, R2, and R1 in options a-d (claim 3). There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim(s) 5, 7, 12, 14, 17, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Drosten et al. "Identification of a novel coronavirus in patients with severe acute respiratory syndrome" N Engl J Med. 2003 May 15;348(20):1967-76. Epub 2003 Apr 10).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

With regard to claim(s) 5 and 7, Drosten teaches identification of the severe acute respiratory syndrome (SARS) viral RNA in affected patients (pg. 1967, results, for example). Specifically, Drosten teaches amplifying a target nucleic acid region of the SARS coronavirus using an oligonucleotide primer designed based on any nucleotide sequence selected from nucleotides 41 to 256 of the nucleotide sequence of an RNA polymerase of the SARS coronavirus as shown in SEQ ID NO: 1 (pg. 1969, RT-PCR for the novel coronavirus; pg. 1970; table 1, protocol 5, BNIinS, GAAGCTATTCGTCACGTTCG; fig. 1, for example). As noted above, a primer having **one** base in common or complementary to **one** base of nucleotides 41 to 256 of SEQ ID NO: 1 is encompassed by the claim language of claim 1. Thus, since the above primer contains all four natural DNA nucleotides, the teachings of Drosten anticipate the claimed invention.

With regard to claim(s) 12, 14, 17 and 19, due to the indefiniteness of the terms F3c, F2c, F1c, R3, R2, and R1 in options a-d (claim 3), i.e. one does not know what sequences are encompassed by such terms, the above primer is thought to meet the limitations of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim(s) 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drosten et al. "Identification of a novel coronavirus in

patients with severe acute respiratory syndrome" N Engl J Med. 2003 May 15;348(20):1967-76. Epub 2003 Apr 10) in view of Notomi et al. ("Loop-mediated isothermal amplification of DNA" Nucleic Acids Res. 2000 Jun 15;28(12):E63).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The methods of the previously applied references have been outlined in the above rejections. The previously applied references do not expressly teach amplification the SARS coronavirus by the LAMP method.

First, as noted above, Drosten teaches amplifying a target nucleic acid region of the SARS coronavirus using an oligonucleotide primer designed based on any nucleotide sequence selected from nucleotides 41 to 256 of the nucleotide sequence of an RNA polymerase of the SARS coronavirus as shown in SEQ ID NO: 1 (pg. 1969, RT-PCR for the novel coronavirus; pg. 1970; table 1, protocol 5, BNIinS, GAAGCTATTCGTCACGTTCG; fig. 1, for example). As noted above, a primer having one base in common or complementary to one base of nucleotides 41 to 256 of SEQ ID NO: 1 is encompassed by the claim language of claim 1. Thus, since the above primer contains all four natural DNA nucleotides, the teachings of Drosten anticipate the claimed invention.

Notomi teaches amplification of a target nucleic acid through the LAMP method (pg.ii, col. 2, materials and methods, for example). Figure 1 further provides a detailed visual schematic representation of the primer design utilized within the LAMP method. Furthermore, Notomi outlines the advantages of the LAMP method such as allowing for high efficiency isothermal amplification conditions without a significant influence of co-present non-target DNA.

In summary, it is submitted that it would have been *prima facie obvious* to a practitioner of ordinary skill in the art at the time of invention to amplify the SARS target nucleic acid taught by Drosten by LAMP since Notomi suggests such a modification to allow for high efficiency.

2. Claim(s) 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drosten et al. "Identification of a novel coronavirus in patients with severe acute respiratory syndrome" N Engl J Med. 2003 May 15;348(20):1967-76. Epub 2003 Apr 10) in view of Buck et al. ("Design Strategies and Performance of Custom DNA Sequencing Primers") BioTechniques. September 1999. 27: Pages 528-536).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The methods of the previously applied references have been outlined in the above rejections. The previously applied references do not expressly disclose the **exact** primer sequence of SEQ ID NO: 10, drawn to the SARS coronavirus.

First, as noted above, Drosten teaches amplifying a target nucleic acid region of the SARS coronavirus using an oligonucleotide primer designed based on any nucleotide sequence selected from nucleotides 41 to 256 of the nucleotide sequence of an RNA polymerase of the SARS coronavirus as shown in SEQ ID NO: 1 (pg. 1969, RT-PCR for the novel coronavirus; pg. 1970; table 1, protocol 5, BNIinS, GAAGCTATTCGTCACGTTCG; fig. 1, for example).

Buck provides a supporting disclosure that expressly provides evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (pg. 532, col. 3, for example), with 69 different primers being submitted (pg. 530, col. 1, for example). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (pg. 530, col. 1, for example). When Buck tested each of the primers selected by the methods of the different labs, Buck found that **EVERY SINGLE PRIMER** worked (pg. 533, col. 1, for example). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, **EVERY SINGLE CONTROL PRIMER** functioned as well (pg. 533, col. 1, for example). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (pg. 535, col. 2, for example)."

Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

Thus, since the claimed primer simply represents a functional homolog of the sequences taught by Drosten, the claimed primers are *prima facie* obvious over Drosten in view Buck.

Conclusion

Claim(s) 5-7, 11, 12, 14, 16, 17, and 19 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5/25/07

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